

We claim:

1 1. A tablet comprising a hydrated form of valacyclovir hydrochloride having a
2 water of hydration content of more than approximately 3% w/w and a particle size of less
3 than approximately 355 μm .

1 2. The tablet according to claim 1, wherein the valacyclovir hydrochloride has
2 a water of hydration content of more than approximately 4% w/w.

1 3. The tablet according to claim 1, wherein the valacyclovir hydrochloride has
2 a water of hydration content of between approximately 3% w/w and approximately 16%
3 w/w.

1 4. The tablet according to claim 1, wherein the valacyclovir hydrochloride has
2 a particle size of less than approximately 250 μm .

1 5. The tablet according to claim 1, wherein the valacyclovir hydrochloride
2 concentration comprises at least approximately 50% w/w of the tablet.

1 6. The tablet according to claim 1, wherein the tablet has a friability and the
2 friability of the tablet does not exceed approximately 1% w/w.

1 7. The tablet according to claim 1, wherein the tablet has a hardness and the
2 hardness of the tablet is at least approximately 10 kP.

1 8. The tablet according to claim 1, further comprising one or more
2 pharmaceutically acceptable excipients.

1 9. The tablet according to claim 8, wherein the pharmaceutically acceptable
2 excipients comprise one or more of a filler, binding agent, disintegrant and lubricant.

1 10. The tablet according to claim 9, wherein the filler comprises one or more of
2 dicalcium phosphate and microcrystalline cellulose.

1 11. The tablet according to claim 9, wherein filler comprises from about 5% to
2 about 40% w/w of the tablet.

12. The tablet according to claim 9, wherein the binding agent comprises one or more of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and polyvinyl pyrrolidone.

13. The tablet according to claim 9, wherein the binding agent comprises between 0.05% and 5% w/w of the tablet.

14. The tablet according to claim 13, wherein a portion of the binding agent is present extra granularly as a dry binding agent.

15. The tablet according to claim 14, wherein the extra granular dry binding agent comprises between approximately 0.05% and approximately 2% w/w of the tablet.

16. The tablet according to claim 9, wherein the disintegrant comprises one or more of clays, kaolin, bentonite, veegum; celluloses, microcrystalline cellulose, croscarmellose sodium, non-ionic disintegrants, and crospovidone.

17. The tablet according to claim 9, wherein the disintegrant comprises from approximately 0.5% to approximately 7% w/w of the tablet.

18. The tablet according to claim 9, further comprising a film coating.

19. A tablet comprising:

an intragranular portion comprising at least approximately 50% w/w of a hydrated form of valacyclovir hydrochloride having a water of hydration content of more than approximately 3% w/w and a particle size less than approximately 355 μm , at least one filler, at least one binding agent, and at least one disintegrant; and

an extragranular portion comprising at least one lubricant, wherein the friability of the tablet does not exceed approximately 1% and the hardness is at least approximately 10 kP.

20. A tablet comprising:

an intragranular portion comprising at least approximately 50% w/w of a hydrated form of valacyclovir hydrochloride having a water of hydration content of more than approximately 3% w/w and particle size less than approximately 355

5 μm , at least one filler, at least one binding agent, and at least one disintegrant
6 present within the granules of the tablet; and

7 an extragranular portion comprising at least one lubricant and at least one
8 binding agent, wherein the friability of the tablet does not exceed approximately
9 1%, the hardness is at least approximately 10 kP.

1 21. The tablet according to claim 20, wherein the binding agent in the
2 intragranular portion and the binding agent in the extragranular portion are of the same
3 material composition.

1 22. A method of treatment of a viral infection in a mammal comprising
2 administering to the mammal one or more tablets to administer an effective anti-viral
3 amount of valacyclovir hydrochloride, the tablet comprising a hydrated form of
4 valacyclovir hydrochloride having a water of hydration content of more than
5 approximately 3% w/w and a particle size of less than approximately 355 μm

1 23. The method of treatment of claim 22, wherein the virus comprises a DNA
2 virus.

1 24. The method of treatment of claim 22, wherein the virus comprises one or
2 more of herpes simplex 1, herpes simplex 2, varicella zoster, cytomegalovirus, Epstein-
3 Barr viruses, human herpes virus-6 (HHV-6), and hepatitis B virus.

1 25. The method of claim 22, wherein the virus comprises one or more of a
2 papilloma or wart virus.

1 26. The method of claim 22, further comprising administering the tablet with a
2 second active compound.

1 27. The method of claim 26, wherein the second active compound comprises
2 zidovudine.

1 28. A process for preparing a tablet comprising at least approximately 50%
2 w/w of a hydrated form of valacyclovir hydrochloride having a water of hydration content
3 of more than approximately 3% w/w and a particle size less than approximately 355 μm

and one or more of at least one binding agent, at least one filler, at least one disintegrant and at least one lubricant, the process comprising:

forming granules of valacyclovir hydrochloride; and

blending an optional portion of the at least one binding agent and a lubricant with the granules,

wherein the hardness of the tablet is at least approximately 10 kP and the friability is not more than approximately 1%.

29. The process according to claim 28, wherein forming the granules comprises:

mixing the valacyclovir hydrochloride and the one or more of the at least one binding agent, the at least one filler, and the at least one disintegrant;

granulating with a granulating solution to form granules;

drying the granules;

blending the granules with a lubricant; and

compressing the blended mixture to form a tablet.

30. The process according to claim 29, wherein blending the granules with a lubricant further comprises blending with a binding agent.

31. The process according to claim 28, wherein forming the granules comprises:

dissolving the binding agent in a granulating solution;

adding and mixing to the granulating solution the valacyclovir hydrochloride and the one or more of the at least one binding agent, the at least one filler, and the at least one disintegrant;

granulating with a granulating solution to form granules;

drying the granules;

9 blending the granules with a lubricant; and

10 compressing the blended mixture to form a tablet.

1 32. The process according to claim 31, wherein blending the granules with a
2 lubricant further comprises blending with a binding agent.

1 33. The process according to claim 28, wherein the granulation results in a
2 fluid uptake of between 8-16%.

1 34. The process according to claim 29, wherein the fluid uptake after
2 granulation comprise between approximately 12 and approximately 16%.

1 35. The process according to claim 29, wherein the granules are dried to a
2 moisture content of more than approximately 4% w/w.

1 36. The process according to claim 29 wherein the extra granular binding agent
2 is first blended with the lubricant before blending with the granules.

1 37. The process according to claim 29 wherein the extra granular binding agent
2 is added separately from the lubricant.

1 38. A method of improving one or both of friability and hardness of a tablet
2 comprising valacyclovir hydrochloride, the method comprising:

3 reducing the particle size of a hydrated form of valacyclovir hydrochloride, the
4 valacyclovir hydrochloride having a water of hydration content of more than
5 approximately 3% w/w.

1 39. The method of improving one or both of friability and hardness of claim
2 38, wherein the particle size is less than approximately 355 μm .

1 40. A method of improving one or both of friability and hardness of a tablet
2 comprising valacyclovir hydrochloride having a particle size of less than approximately
3 355 μm , the method comprising:

4 forming the tablet from a hydrated form of valacyclovir hydrochloride having a
5 water of hydration content of more than approximately 3% w/w.

1 41. A tablet comprising a hydrated form of valacyclovir hydrochloride
2 characterized by the absence of colloidal silicon dioxide and extra granular
3 microcrystalline cellulose.

1 42. The tablet of claim 41, wherein the valacyclovir hydrochloride has a water
2 of hydration content of more than approximately 3% w/w and a particle size of less than
3 approximately 355 μm .

1 43. The tablet of claim 1, which is further free or substantially free of both
2 silicon dioxide and microcrystalline cellulose.